

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

X

IN RE: WORLD TRADE CENTER DISASTER
SITE LITIGATION

21 MC 100 (AKH)

THIS DOCUMENT APPLIES TO ALL IN RE
WORLD TRADE CENTER DISASTER SITE
LITIGATION

X

**MEMORANDUM OF LAW IN OPPOSITION
TO MOTION TO MODIFY SUBPOENA *DUCES TECUM*
AND FOR PROTECTIVE ORDER**

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The Subcontractor Defendants¹ submit this memorandum of law in opposition to the motion by the City of New York for an order modifying the subpoena *duces tecum* issued to the Fire Department of the City of New York (the “FDNY”) and for a protective order.

PRELIMINARY STATEMENT

The Subcontractor Defendants served a subpoena *duces tecum* on the FDNY seeking information and data underlying 28 published studies performed by the FDNY on the alleged health effects sustained by its personnel as a result of the rescue, recovery, and debris removal operations following the terrorist attacks on the World Trade Center on September 11, 2001. Specifically, the Subcontractor Defendants seek three categories of information: (1) the foundational documents for the studies, including study protocols and methodological details; (2) the entire set of raw data collected for use in the studies; and (3) documents related to study

¹ These defendants are as follows: A. Russo Wrecking, Inc., Anthony Cortese Specialized Hauling, LLC, Atlantic-Heydt Corporation, Berkel & Company Contractors, Inc., Big Apple Wrecking & Construction Corp., Breeze Carting, Inc., Breeze National, Inc., Brer-Four Transportation, Buro Happold Consulting Engineers, P.C., C.B. Contracting Corp., Canron Construction Corp., Component Assembly Systems, Inc., Cord Contracting Co., Inc., Dakota Demo-Tech, Diamond Point Excavating Corporation, Diversified Carting, Inc., DMT Enterprise, Inc., E.J. Davies, Inc., Eagle One Roofing Contractors, Inc., En-Tech Corporation, Ewell W. Finley, P.C., Executive Medical Services, P.C., Fleet Trucking, Inc., Francis A. Lee Company, FTI Trucking Corp., Gilsanz Murray Steficek, LLP, Goldstein Associates Consulting Engineers, P.C., Hallen Welding Service, Inc., HP Environmental, Inc., Hudson Meridian Construction Group, LLC, J.P. Equipment & Rental Materials, Inc., La Strada General Contracting Corp., Laquila Construction, Inc., Leslie E. Robertson Associates, R.L.L.P., Liberty Mutual Insurance Company, Lockwood Kessler & Bartlett, Inc., Lucius Pitkin, Inc., LVI/Mazzocchi Wrecking, Inc., LZA Technology – a division of Thornton Tomasetti, Manafort Brothers Incorporated, Moretrench American Corp., MRA Engineering, P.C., Mueser Rutledge Consulting Engineers, Nacirema Industries, Inc., New York Crane & Equipment Corp., Nicholson Construction Company, Peter Scalamandre and Sons, Inc., Pinnacle Environmental Corp., Pro Safety Services, Inc., PT&L Contracting Corp., Robert L. Gerosa, Inc., Robert Silman Associates, P.C., Rodar Enterprises, Inc., Royal GM Inc., SAB Trucking, Inc., Safeway Environmental Corp., Semcor Equipment & Manufacturing Corp., Silverite Contracting Corp., Simpson Gumpertz & Heger, Inc., Skanska Koch, Inc., Skidmore, Owings & Merrill, LLP, Thornton Tomasetti, Inc., Total Safety Consulting, LLC, Tucci Equipment Rental Corporation, Vollmer Associates LLP, Weeks Marine, Inc., Weidlinger Associates P.C., Wolkow Braker Roofing Corp., WSP Cantor Seinuk, Yannuzzi & Sons, Inc., and Yonkers Contracting Company, Inc.

publication, including drafts of the studies, peer-review comments, and communications among co-authors. Discovery of this data is essential to a scientific defense against the plaintiffs' claims of WTC-related illnesses because the defendants' experts must have an opportunity to test the validity of the studies and to understand data not reported by the authors of the studies. The City opposes disclosure of the raw data, citing certain statutes and regulations it believes prohibits such disclosure. Nonetheless, the City has failed to articulate why these provisions would constrain disclosure in the face of a reasonable and appropriate protective order. In fact, as the Court has already recognized, the only true issue here is the proper scope of a protective order and redaction of certain names and Social Security numbers, all of which is agreeable to the Subcontractor Defendants.

STATEMENT OF FACTS

Following discussions with the City concerning the production of information and data underlying published studies performed by the FDNY on the alleged health effects sustained by its personnel at the World Trade Center Site, the Subcontractor Defendants served a subpoena *duces tecum* on the FDNY.² Despite several subsequent discussions concerning the possible production of documents, the parties have been unable to agree on the scope of a protective order. Although the Subcontractor Defendants do not object to the redaction of the names and Social Security numbers of study participants who were never plaintiffs in the litigation, the City refuses to produce the names and Social Security numbers of study participants who were plaintiffs in the litigation and who discontinued or settled their lawsuits. The City also refuses to produce other significant information concerning study participants, including complete street

² During the conference before the Court on November 22, 2011, which addressed the status of discovery and the subpoena *duces tecum*, the Court asked whether the Subcontractor Defendants could serve the subpoena the next day. [Declaration of Robert S. Deutsch, Exhibit A, p. 13.] The Subcontractor Defendants served the subpoena on November 23, 2011.

addresses, race, sex, height, and weight, as well as complete dates of birth, dates of death, dates of employment, and dates of diagnosis.

Although the Subcontractor Defendants contend that the language of Protective Order No. 3 Governing the Disclosure of Confidential Medical Information, which the Court issued on July 15, 2009 [Declaration of Robert S. Deutsch, Exhibit B], provides adequate protection to the participants in the FDNY studies, the Subcontractor Defendants attempted to address the City's concerns regarding disclosure of certain data by agreeing to modify the order to include a prohibition against identifying or attempting to identify any participants who are not plaintiffs in the litigation. However, in view of the City's untenable proposals, the parties have been unable to agree on language to include in a protective order.

On December 16, 2011, the City provided a draft of a protective order governing the disclosure of confidential medical information from the FDNY World Trade Center Medical Monitoring and Treatment Programs (the "FDNY WTC MMTP") [Deutsch Decl., Exhibit C]. The draft defined "FDNY WTC MMTP Confidential Medical Information" as any documents, information, or things which concern or relate to medical or demographic information of participants in the FDNY WTC MMTP [*id.* at ¶ 3], limited the disclosure of information to counsel for the Subcontractor Defendants, Plaintiffs' and Defendants' Liaison Counsel, and outside experts [*id.* at ¶ 4], mandated the execution of an unspecified "non-disclosure undertaking" [*id.* at ¶ 6], and required conferring with counsel for the City before using any document containing confidential medical information during a deposition in order to allow the City an opportunity to seek any additional protective relief [*id.* at ¶ 7].

Instead of attempting to negotiate language to which the parties could agree, the City continued to propose requirements that became even more onerous. Thus, for example, on

December 19, 2011, the City provided a revised draft of a protective order [Deutsch Decl., Exhibit D] defining “FDNY WTC MMTP Confidential Medical Information” as any documents, information, or things which concern or relate to demographic information (including, without limitation, race, sex, height, address, and dates of birth, death, hire, or retirement) or medical information [*id.* at ¶ 3] and imposing the additional burden of conferring with counsel for the City before using any document containing confidential medical information in any filing or other proceeding in the litigation in order to allow the City an opportunity to seek any additional protective relief [*id.* at ¶ 7].

As a result of the City’s requests to include unnecessary and increasingly burdensome requirements, the Subcontractor Defendants have not reached an agreement with the City concerning the scope and terms of a protective order. The Subcontractor Defendants contend that Protective Order No. 3 Governing the Disclosure of Confidential Medical Information, supplemented by a provision prohibiting the parties from ascertaining or attempting to ascertain the identities of study participants who are not plaintiffs in the litigation, provides reasonable and adequate protection to the research subjects.

I. DISCOVERY OF THE UNDERLYING DATA IS ESSENTIAL TO A DEFENSE AGAINST THE PLAINTIFFS’ CLAIMS.

Discovery of the information and data underlying the published studies is essential to a scientific defense against the plaintiffs’ broad claims of WTC-related illnesses and health effects. The Subcontractor Defendants anticipate that the plaintiffs will rely on numerous peer-reviewed studies to support both general and specific causation claims and that treating physicians and experts will cite such studies. Even if the original authors of the studies are not witnesses, the articles themselves can reasonably be expected to be relied upon by plaintiffs’ testifying experts.

While most of the affidavit of David J. Prezant in support of the City's motion is devoted to legal arguments concerning confidentiality, only two paragraphs of the affidavit briefly address the City's contention that the Subcontractor Defendants do not need the data underlying the published studies. [Affidavit of David J. Prezant, ¶¶ 23-24.] Dr. Prezant asserts merely that "the subpoenaing parties have no *apparent* need for the demographic data." [Id. at ¶ 24] (emphasis added). As demonstrated in the affidavits accompanying this opposition, a thorough analysis of the data underlying the published studies is necessary in order to test the validity of the studies and to understand important aspects of the data collected but not used by the authors of the studies.

As David Posner, a pulmonologist, explains in his affidavit, in order to verify or refute the interpretations of the authors of the studies, the demographics and medical risk factors must be known. [Affidavit of David Posner, ¶ 6.] Raw data, including race, sex, height, date of birth, date of death, date of hire, and date of retirement must be provided in order to understand the data that was collected but not used or reported. [Id.] In addition, the data the City refuses to disclose includes information that is necessary in determining predicted values for pulmonary function evaluation. [Id. at ¶¶ 7-8.] Similarly, as Kenneth A. Mundt, an epidemiologist, explains in his affidavit, the most important determinants of disease risk in humans are age, sex, race, height, and weight. [Affidavit of Kenneth A. Mundt, ¶ 4.] Additional information relevant to occupational and environmental risks includes location and dates of employment and residence. [Id.] All of this information is needed to evaluate the underlying relationships between occupational and environmental exposures and diseases as described in the articles and the conclusions contained in the articles. [Id.]

Indeed, this Court directed the City to “give all fields,” to “redact the name,” and to “[c]reate a code so the names are not revealed.” [Deutsch Decl., Exhibit A, p. 12.] With respect to the “threshold” issue of what data is actually discoverable, the Court explained that “[a]ll of it” is discoverable. [*Id.* at p. 13.]

It’s all in the hopper because nobody knows the impact of prior medical information on a disease that is alleged to have occurred by reason of working on the pile. So all those fields are potentially relevant. What you need to do is to safeguard the individual’s name, and I am going to give you and deal with that in a protective order.

Id.

II. FEDERAL LAW APPLIES TO THE SUBPOENAED DATA.

Contrary to the City’s erroneous assertion [Memorandum of Law of City of New York, pp. 6-7], state law does not supply the rule of decision with respect to privilege because these cases arise under federal law. Any state law claims are merely pendent claims under the Court’s supplemental jurisdiction. “It is axiomatic that state privilege laws do not govern in federal question cases.” *In re Zyprexa Products Liability Litigation*, 254 F.R.D. 50, 52 (E.D.N.Y. 2008). Federal law with respect to privileges applies even where a federal question case contains pendent state law claims. *Id.*; *von Bulow v. von Bulow*, 811 F.2d 136, 141 (2d Cir. 1987) [holdings that asserted privileges are governed by federal law are consistent with the legislative history of Rule 501 because the intent was that the federal law of privileges should be applied with respect to pendent state law claims when they arise in a federal question case].

This litigation is a federal question case by virtue of the Air Transportation Safety and System Stabilization Act, 49 U.S.C. § 40101, *et seq.* (“ATSSSA”). Accordingly, the federal law of privilege controls the question as to whether any privileges asserted by the City should be recognized.

III. THE NEW YORK DOCTOR-PATIENT PRIVILEGE DOES NOT APPLY.

The City asserts first that the New York doctor-patient privilege, codified in CPLR § 4504(a), applies to the subpoenaed data and requires withholding identifying information. Since state law does not supply the rule of decision with respect to privilege, the New York doctor-patient privilege does not apply. “No physician-patient privilege exists under federal common law.” In re Zyprexa Products Liability Litigation, *supra*, 254 F.R.D. at 52. *See also Jaffee v. Redmond*, 518 U.S. 1, 10 (1996).

Even if the doctor-patient privilege applied in litigation based on federal question jurisdiction, the provisions of CPLR § 4504 do not pertain to the underlying research study data because it was not acquired by a physician attending a patient for treatment purposes. “The physician-patient privilege generally does not extend to information obtained outside the realms of medical diagnosis and treatment.” In re Grand Jury Investigation in New York County, 98 N.Y.2d 525, 779 N.E.2d 173, 749 N.Y.S.2d 462, 465 (2002). Here, the relevant information has been collected for research purposes, not for treatment of any specific individual. Thus, the underlying data is discoverable in litigation based on federal question jurisdiction, subject to an appropriate protective order.

Although the City does not dispute that current plaintiffs have waived any doctor-patient privilege by placing their medical condition at issue, the City asserts that plaintiffs who discontinued or settled their lawsuits have not waived the doctor-patient privilege with respect to the current actions in which they are not parties. [Mem. of Law of City of New York, p. 9-10.] Even assuming the existence of such a privilege as to study participants who were never plaintiffs in the litigation, the privilege would not apply to former plaintiffs. In support of the proposition that the privilege exists as to former plaintiffs, the City cites two cases, Kohn v.

Fisch, 262 A.D.2d 535, 692 N.Y.S.2d 429 (2d Dep't 1999), and Strong v. Brookhaven Memorial Hospital Medical Center, 240 A.D.2d 726, 659 N.Y.S.2d 104, 105 (2d Dep't 1997), which are factually distinguishable from this litigation. The cases did not involve participation in research studies, publication of the results of studies, federal funding of studies, or limited access to underlying data. In those cases, the Appellate Division, Second Department, affirmed orders precluding discovery of the plaintiffs' psychiatric and psychological records after the plaintiffs withdrew their claims for psychological injuries because the records were no longer relevant to the conditions at issue. Moreover, despite the City's contention [Mem. of Law of City of New York, p. 10], the medical conditions of the participants who discontinued or settled their cases, as documented in the published studies, is potentially relevant to issues of causation in this litigation.³

**IV. 42 U.S.C. § 289 REGARDING INSTITUTIONAL
REVIEW BOARDS DOES NOT PREVENT
DISCLOSURE OF THE SUBPOENAED DATA.**

42 U.S.C. § 289(a) requires the establishment of an "Institutional Review Board" ("IRB") to review biomedical and behavioral research of an entity seeking federal funding for research. With respect to the City's assertion concerning IRB-approved consent forms promising that the *names* of participants will not be identified [Mem. of Law of City of New York, p. 15], the Subcontractor Defendants have already agreed to the redaction of the names and Social Security numbers of the study participants who are not plaintiffs in the litigation. Moreover, the Subcontractor Defendants do not seek to identify the research subjects who are not plaintiffs but, rather, seek the production of data underlying the studies for purposes of expert review. A

³ If the City is prepared to allow the Subcontractor Defendants to attempt to replicate the results of tests for a statistically meaningful sample of the study population [Mem. of Law of City of New York, p. 14], the City cannot maintain that a privilege exists with respect to the entire study population.

reasonable and appropriate protective order, as proposed by the Subcontractor Defendants, would provide adequate protection to the participants in the FDNY studies.

**V. 42 U.S.C. § 241(d) REGARDING PRIVACY OF
RESEARCH SUBJECTS DOES NOT PREVENT
DISCLOSURE OF THE SUBPOENAED DATA.**

42 U.S.C. § 241(d), which provides for the protection of the privacy of individuals who are research subjects, authorizes the withholding of names or other identifying characteristics of such individuals. The Subcontractor Defendants have already agreed to the redaction of the names and Social Security numbers of the study participants who are not plaintiffs in the litigation.

Courts that have considered the requirements of 42 U.S.C. § 241(d) have found that it does not prevent disclosure of raw data underlying studies in the context of litigation. For example, in Murphy v. Philip Morris Inc., 2000 U.S. LEXIS 21128 (C.D. Cal. 2000), the Court granted a motion to compel production of documents in response to a subpoena *duces tecum* seeking raw data underlying an epidemiological study that was federally funded. The third-party opposed the motion on the ground that disclosure would abrogate statutory prohibitions against the disclosure of the identities of study participants. After accepting the assurances by Philip Morris that it had no intention of using the raw data to identify any of the study participants, the Court considered the requirements of 42 U.S.C. § 241(d) and 45 C.F.R. § 46.116(a) that the names and “identifying characteristics” of the subjects not be disclosed. The Court found “that Philip Morris’ interest in disclosure of the redacted raw data outweighs the interest of the public in non-disclosure of that redacted data” and established a protective order to protect the confidentiality of the study participants. Murphy v. Philip Morris Inc., *supra*, 2000 LEXIS 21128 at *11-12.

Here, the Subcontractor Defendants do not seek to identify the research subjects who are not plaintiffs but, rather, seek the production of data underlying the studies for purposes of expert review. A reasonable and appropriate protective order, as proposed by the Subcontractor Defendants, would provide adequate protection to the participants in the FDNY studies.

**VI. THE HEALTH INSURANCE PORTABILITY AND
ACCOUNTABILITY ACT DOES NOT PREVENT
DISCLOSURE OF THE SUBPOENAED DATA.**

The Health Insurance Portability and Accountability Act (“HIPAA”)⁴ controls the use and disclosure of “protected health information” by “covered entities.” 45 C.F.R. §§ 164.502, 160.103. A “covered entity” is defined as a health plan, a health care clearinghouse, or a health care provider who transmits any health information in electronic form. 45 C.F.R. § 160.103.

A covered entity may disclose protected health information in the course of any judicial or administrative proceeding: . . . [i]n response to a subpoena, discovery request, or other lawful process, that is not accompanied by an order of a court or administrative tribunal, if: . . . [t]he covered entity receives satisfactory assurance . . . from the party seeking the information that reasonable efforts have been made by such party to secure a qualified protective order

45 C.F.R. § 164.512(e)(1)(ii)(B). A “qualified protective order” is an order or a stipulation by the parties that “[p]rohibits the parties from using or disclosing the protected health information for any purpose other than the litigation or proceeding for which such information was requested; and . . . [r]equires the return . . . or destruction of the protected health information (including all copies made) at the end of the litigation or proceeding.” 45 C.F.R. § 164.512(e)(1)(v).

Assuming the applicability of HIPAA to the FDNY studies, a qualified protective order would permit disclosure of the data underlying the studies. As the Court noted in In re Zyprexa Products Liability Litigation, “HIPAA provides for a subpoena process that does not require

⁴ This statute was not cited in the City’s objections to the subpoena to produce documents and information under Rule 45, which the City served on December 7, 2011. [Declaration of Kenneth A. Becker, Exhibit D.]

notice to patients. Pursuant to HIPAA regulations, Lilly could subpoena (de-identified) medical records without notifying the patient, so long as Lilly provided . . . adequate assurance that it had made reasonable efforts to seek a HIPAA-qualified protective order.” In re Zyprexa Products Liability Litigation, *supra*, 254 F.R.D. at 56 (citing 45 C.F.R. § 164.512(e)(1)(ii)(B)). Accordingly, a qualified protective order, as proposed by the Subcontractor Defendants, would address the City’s concerns regarding disclosure of the research data.

VII. A PROTECTIVE ORDER PROHIBITING ANY ATTEMPT TO IDENTIFY THE SUBJECTS OF THE STUDIES PROVIDES REASONABLE AND ADEQUATE PROTECTION.

The decision of the Second Circuit in In re Application of American Tobacco Co., 880 F.2d 1520 (2d Cir. 1989), a case with a remarkably similar factual background, is particularly instructive on the issue of protective orders. In that case, Mount Sinai School of Medicine and The American Cancer Society appealed from an order of the Southern District of New York holding them in civil contempt for failing to comply with orders requiring them to respond to subpoenas served by The American Tobacco Company, R.J. Reynolds Tobacco Company, and Philip Morris, Inc., requesting research data as to studies on the dangers of smoking cigarettes in combination with occupational exposure to asbestos. The tobacco companies expected that the plaintiffs would rely on expert testimony that would rely on studies by members of the non-parties and sought to subpoena the data underlying those studies. The non-parties challenged orders that denied their motion to quash the subpoenas on grounds of privilege and denied in part their motion for a protective order permitting redaction of the subpoenaed material to prevent identification of the subjects of the research.

The district court's protective order allowed the non-parties to redact the names of the participants in the studies, street addresses, towns or villages,⁵ Social Security numbers, employers, and union registration numbers. The non-parties contended that they should also be allowed to redact counties of residence and union local data and to summarize birth and death dates by decade. They asserted that without these modifications, the tobacco companies and others could identify the subjects of the studies.

The Second Circuit upheld the orders of the district court and determined that the protective order fashioned by the district court was not an abuse of discretion. In re American Tobacco Co., supra, 880 F.2d at 1531. The Court rejected the claims of an expert's privilege and a research scholar's privilege. Id. at 1527-1530. With respect to the district court's protective order, the Court refused to grant further redactions as requested by the non-parties. Id. at 1530. Finally, the Court rejected the contention that further redaction was required in order to preserve the physician-patient privilege and determined that, assuming the existence of facts prerequisite to the assertion of such a privilege, a protective order providing for confidentiality would adequately preserve the privilege. Id. at 1530-1531.

The City suggests that the subjects of the FDNY studies are at an increased risk of identification, requiring a greater redaction of data than was ordered in American Tobacco. [Mem. of Law of City of New York, pp. 12-13.] Specifically, the City contends that it would be easier to identify the subjects of the FDNY studies, who come from a discrete population of FDNY personnel, than the subjects of the studies in American Tobacco, who came from a diverse population of asbestos workers. [Id.] However, as the City notes, the Court in American

⁵ As explained in the Affidavit of Dr. Mundt, residence is information specifically relevant to occupational and environmental risks and is needed in order to evaluate the underlying relationships between occupational and environmental exposures and diseases as described in the articles and the conclusions contained in the articles. [Mundt. Aff., ¶ 4.]

Tobacco found that even if it was possible for the tobacco companies to determine the identities of some of the research participants from the information provided after the redactions ordered by the district court, the protective order enjoined them from doing so. In re American Tobacco Company, *supra*, 880 F.2d at 1530. A similar provision in this litigation, supplementing Protective Order No. 3 Governing the Disclosure of Confidential Medical Information, would provide reasonable and adequate protection to the participants in the FDNY studies.

CONCLUSION

The Court should deny the motion by the City of New York to modify the subpoena *duces tecum* issued to the FDNY and for a protective order and direct that the FDNY comply with the subpoena, subject to Protective Order No. 3 Governing the Disclosure of Confidential Medical Information, supplemented by a provision prohibiting the parties from identifying or attempting to identify any study participants who are not plaintiffs in the litigation.

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January 11, 2012

Respectfully submitted,



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